Group Leader-AR&D (Newtown, PA) – Lead research and development of quantitative and qualitative analytical methods of invitro-release drug delivery systems in pharmaceutical R&D process for IVRT/IVPT topical products using Malvern; Lead analytical method development and method validation for assay, Impurity, Residual solvent, cleaning residue, particle size, elemental impurity and Dissolution using HPLC/UPLC, GC, ICP-MS, Malvern Particle analyzer for API, excipients and finish products; Initiate, Review and revise Test procedures, SOP'S, Validation protocol and reports, In-process and finished product specification, technical documents such as assessment reports for elemental impurity and Residual solvent; Oversee troubleshooting and laboratory investigation, identify root cause and implement corrective action and preventive action; Participate in writing, assembling and reviewing regulatory dossiers in Module-3 for ANDA projects for submission; Conduct regular analysis of pharmaceutical products, in -process, raw material and stability samples at pre-ANDA stages; Supervise 2 chemists.

Must have a Master's Degree or its equivalent (Bachelor's Degree plus 5 years experience inclusive of 2 years experience in job offered) in Chemistry, Organic Chemistry, or Pharmaceutical Science plus 2 years experience in job offered. Require skills and knowledge of HPLC/UPLC, Method development/validation, ICP-MS, SOP's, ANDA, GC, Dissolution.

Job location: Newtown, PA. Submit résumé referencing job code CHD004 to HR, KVK-Tech, Inc., 110 Terry Drive, Newtown, PA 18940